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Kimberly Topper
Food and Drug Administration, CDER
Advisors and Consultants Staff, HFD-21
5600 Fishers Lane
Rockdale, MD 20857

RE: Docket #01N-0256

Dear Ms. Topper:

I am writing to the Anesthetic and Life Support Drugs Advisory committee with reference to the meeting to be held on September 13th and 14th. I am writing to support the medical use of opiate analgesics in patients with chronic pain of nonmalignant etiology.

My basic training is in neurosurgery but I have always had an active interest in pain management. In 1997 I became Board Certified in pain medicine and at the present time approximately 90% of my practice is involved in pain management. This includes conventional pain management as well as pharmacotherapy. In addition I am the medical director of a multi-disciplinary "behavior modification" type of pain clinic.

In 1994 the American Pain Society and the American Academy of pain medicine came out with a joint position statement advocating the use of opioids for the treatment of chronic nonmalignant pain. As is true of most physicians in my generation, I initially began to prescribe narcotics in this manner with some trepidation. However, trusting my more experienced colleges in pain medicine I began to use these medications cautiously. In 1998 I attended a meeting sponsored by Dr. Russell Portnoy which was a joint meeting between pain physicians and addiction medicine specialists. I attended that meeting primary to learn if the addiction physicians endorsed the position of the pain physicians with regard to the use of opioids for chronic nonmalignant pain. I found that they did.

Over the years as my experience grew so did my confidence. I have treated a number of addicts knowingly and unknowingly during the past several years and I have not found them to represent a problem. I have learned that addicts are unable to control the use of their medication and have engaged in drug seeking behavior. Their medication dosages have escalated without my permission and correspondingly their level of function has decreased. I have found in contrast that the vast majority of my patients who suffer from chronic pain once the appropriate dosage is identified are able to control their medication and their level of function improves significantly.

I have treated addicts who are suffering from a chronic pain condition but I approach them differently than someone who is not addicted to the medication. There are a number of options available to them including keeping them "on a shorter leash." By that I mean giving them a small amount of drugs and seeing them frequently on a regular basis. Another method would be the use of an implantable infusion pump which allows us to control their medication when they are unable to. There are other modalities that I use to treat addicts other than drugs and this would include our pain clinic and spinal cord stimulation.

Diversion is a concern to all of us. I have utilized drug screens as part of my practice. I have all my patients sign an opioid contract which includes in it the statement that I can get a drug screen any time I want. I have found these drug screens to be very useful. For example, if I have a patient on opioids and they test negative for opioids then I have to suspect that they are selling the drugs. I can also see whether or not they are taking any other street drugs and if they are I can then exercise an option of not prescribing for them or, again, "reining them in."

I do not believe that I have produced addiction in very many if any patients who where not already addicted. I have had a couple of patients tell me that they felt that they were "getting to like the drugs too much" and we were able to withdraw them from the narcotics very easily. I always openly discuss addiction with my patients and tell them what to watch for. Tolerance is another problem. I have found that in contrast to what I have been told by many experts tolerance is a real problem. However, tolerance is usually specific to one drug at a time and I have been able to control tolerance by weaning a patient off of one narcotic and slowly instituting a second one until they are completely switched over to the new drug. After a period of time they seem to lose the tolerance to the first drug and one can then reverse the process and go back to the initial drug if desired.

Admittedly, these drugs are very serious and potentially dangerous drugs and physicians need to know how to prescribe them, what to watch for, and how to manage various problems. This, however, is not unique to opioids but includes most drugs. Most prescription medications by their very nature have the risk of side effects associated with them and require knowledge, experience, and conscientious attention to detail with regard to prescribing practices.

As I'm sure the committee is aware, the activities of Dr. Kevorkian and other individuals of his ilk are what has led to an increased incidence in proper pain management. This is of course reflected in the joint commission on hospital accreditations current emphasis on pain management and its identification of pain as the "fifth vital sign." I would certainly hate to have us go back to the repressive policies of old which severely handicapped our ability to take care of these unfortunate individuals. As physicians we are charged with "relieving the pain and suffering of our patients." I believe that opioids provide a safe and effective method of achieving this goal.

Sincerely yours,

Dexter D. Koons, M.D.

DDK/alw